

REMARKS

Paragraph [00131], at page 25 of the originally filed specification has been amended to correct a typographical error. No new matter has been added.

Claims 1-38 are pending. Claims 5-7 have been amended to maintain consistency with the antecedent basis. Support for amended claims 5-7 can be found throughout the originally filed specification, for example at page 25, paragraph [00129]. No new matter has been added, and Applicants believe that the amendment does not change the scope of claims 5-7. Claims 12-38 have been withdrawn.

Entry of the amendments and foregoing remarks are respectfully requested.

I. CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 2-7 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

First, the Examiner contends that the recitation of the particle size in claims 2-5 is indefinite because the placebo cushioning component is not itself a bead or particle, but rather merely a component of a bead, particle, granule or pellet. Applicants disagree, for the reasons discussed below.

Claims 2-4¹ specify a particle size of the placebo cushioning component of claim 1. Contrary to the Examiner's assertion that the placebo cushioning component is not itself a particle (see Office Action at page 2), Applicants assert that the placebo cushioning component itself can encompass a particle (see specification at page 8, paragraph [0037]), and claims 2-4 recite size ranges of placebo cushioning component particles. Thus, claims 2-4 should not be interpreted to read on the size of the particle, bead, granule or pellet of the active cushioning component, as the Examiner suggested (see Office Action at page 3). As illustrated in Figure 1 of the specification as originally filed, the active cushioning component bead (or particle) of the

¹ The Examiner erroneously stated that claims 2-5 refer to the particle size of the placebo cushioning component (Office Action at page 2). Only claims 2-4 refer to the particle size of the placebo cushioning component. Claim 5, as amended, refers to the relative amount by weight of the active-loaded particles based on the total weight of the active cushioning component.

invention is prepared by co-processing of an active-loaded bead (or particles) and a placebo cushioning component bead (or particle). Thus, the placebo cushioning component can encompass a particle that is characterized by a particle size, and which is not the same as a bead or particle of the active cushioning component. The specification as originally filed supports Applicants' position. For example, the specification teaches that the "placebo cushioning component" can encompass a bead, particle or granule, and that the "particle size" refers to the mean diameter of the particles, including, *e.g.*, particles of the placebo cushioning component (see the specification at page 8, paragraphs [0037] and [0038]). Thus, the placebo cushioning component can encompass a particle having a particle size as specified in claims 2-4. Therefore, claims 2-4 are not indefinite, and this rejection should be withdrawn.

In addition, the Examiner contends that claim 5 is indefinite because it refers to the particle size of the placebo cushioning component (see Office Action at page 2). The Examiner is in error and the Applicants respectfully disagree. Claim 5 does not refer to the particle size of the placebo cushioning component, but instead is directed to the relative amount of the active loaded particles in the active cushioning component. Further, claim 5 should not be interpreted to read on the size of the particle, bead, granule or pellet of the active cushioning component, as the Examiner suggested (see Office Action at page 3). Rather, claims 5 should be interpreted to read on the relative amount by weight of the active-loaded particles based on the total weight of the active cushioning component. Therefore, claim 5 is not indefinite, and this rejection should be withdrawn.

Second, the Examiner contends that the recitation of the relative amount of the active-loaded particles in claims 6 and 7 is indefinite because the active-loaded component is merely a part of the bead, granule, particle or pellet and it is unclear how such component can have a particle size (see Office Action at page 3). Contrary to the Examiner's assertion (see office Action at page 3), claims 6 and 7 do not refer to particle size of the active-loaded particles (even though the active-loaded particles can have a particle size). Further, contrary to the Examiner's interpretation of claims 6-7 (see Office Action at page 3), claims 6 and 7 should not be interpreted to read on the relative amount of the active agent. Rather, claims 5-7 recite the relative amount by weight of the active-loaded particles based on the total weight of the active cushioning component. Applicants note that the active-loaded particles are not the same as "the

active agent,” referred to in the Office Action, because the active-loaded particles may comprise more than one active agents and may comprise inactive ingredient/s (see the specification at page 19, paragraphs [0097] and [00101]). The active-cushioning component comprises active-loaded particles, thus specifying an amount of the active-loaded particles by weight based on the total weight of the active cushioning component is not indefinite. Therefore, claims 6 and 7 are not indefinite, and this rejection should be withdrawn.

In view of the above, the rejection under 35 U.S.C. § 112, second paragraph, of claims 2-7 should be withdrawn.

II. DOUBLE PATENTING REJECTION

Claims 1-11 are rejected on the ground of nonstatutory, obviousness-type double patenting as allegedly being unpatentable over claims 16-30 of U.S. Patent No. 5,780,055 to Habib *et al.* (“Habib”) in view of U.S. Patent No. 4,910,023 to Botzolakis *et al.* (“Botzolakis”). Applicants respectfully disagree.

Claims 1-11 specify that the admixture of the placebo cushioning component and active-loaded particles is freeze-dried to form the active cushioning component. Claims 16-30 of Habib are directed to a tablet comprising a biologically active ingredient-loaded beads and cushioning beads, wherein only the cushioning beads were prepared by freeze drying prior to combining them with the active ingredient-loaded beads (col. 87, *ll.* 58-64). Claims 16-30 of Habib do not specify freeze-drying of the admixture of the placebo cushioning component and the active-loaded particles, and thus fail to teach or suggest preparation of the active cushioning component of the claims of the present application. Further, as discussed below, Habib also does not teach or suggest freeze-drying of the active-loaded particles alone or together with the placebo cushioning component. Botzolakis fails to remedy the deficiencies of Habib. Botzolakis teaches oven drying of the mixture of a drug with microcrystalline cellulose, crospovidone and water (see col. 2, *ll.* 35-64; col. 3, *ll.* 36-53; and col. 4, *ll.* 10-25). As discussed below, oven drying is distinct from freeze-drying and achieves different results than freeze-drying. Thus, like Habib, Botzolakis fails to teach or suggest freeze-drying of the admixture of the placebo cushioning component and the active-loaded particles to form the active cushioning component of the claims.

In view of the above, Applicants believe that claims 1-11 are patentably distinct from claims 16-30 of Habib over Botzolakis. Therefore, this rejection should be withdrawn.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

Claims 1 and 5-11 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Botzolakis. Applicants disagree, for the reasons discussed below.

The standard for anticipation is set forth in *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987): “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *See also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) (holding that “[t]he identical invention must be shown in as complete detail as is contained in the...claim”). *See also In re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q.2d 1655, 1657 (Fed. Cir. 1990); *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375, 62 U.S.P.Q.2d 1917, 1921 (Fed. Cir. 2002).

Botzolakis discloses an admixture of a drug with silicon dioxide, microcrystalline cellulose and crospovidone, where the admixture is dried in an oven, milled and tabletted (see col. 2, *ll.* 35-64; col. 3, *ll.* 36-53; and col. 4, *ll.* 10-25). However, as the Examiner acknowledges (see Office Action at page 5), the combination disclosed in Botzolakis is not freeze-dried, but rather oven dried. Contrary to the Examiner’s assertion that the freeze-drying step of the claims and the oven drying step of Botzolakis produce the same result (see Office Action at page 5), for the reasons discussed below, the freeze-drying does not yield the same result or composition as oven drying disclosed in Botzolakis.

As evident from the disclosure of the invention, the freeze drying of the admixture of the placebo cushioning component and the active-loaded particles creates the unexpected cushioning characteristic of the active cushioning component and produces a very porous layer of cushioning component that surrounds the active-loaded particles (see the specification at page 16, paragraph [0085]). In contrast, oven-drying is accompanied by a shrinking process, resulting in denser and less porous products (see Habib at col. 52, *ll.* 60-65). The characteristics of the active cushioning component achieved through the freeze-drying allow coatings of the active-

loaded particles to withstand compression forces during the tableting process as high as 1000 kg or more (see the specification at page 16, paragraph [0085]). Furthermore, the present specification teaches that the freeze-drying creates a non-hygroscopic active cushioning component that does not require any special handling or packaging, thereby reducing costs associated with the use of the existing technology (see specification at page 16, paragraph [0085]). Thus, the freeze-drying step of the pending claims produces a composition that is not the same as the composition produced by the oven-drying described in Botzolakis, and consequently Botzolakis fails to teach an essential element of the present invention.

In view of the foregoing remarks, it is submitted that the present invention is not anticipated by Botzolakis, and thus, the rejection is in error and should be withdrawn.

IV. CLAIM REJECTION UNDER 35 U.S.C. § 103(a)

A. Claims 1-11 Are Patentable Over Botzolakis in View of Habib.

Claims 1-11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Botzolakis in view of Habib. Applicants respectfully disagree.

In the consideration and determination of obviousness under 35 U.S.C. § 103(a), the Supreme Court in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 10 (1966) stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter to be patented.

The standard set forth in *Graham* is a broad inquiry which invites looking at any secondary considerations that would prove instructive in the obviousness analysis. *KSR Intern. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1736 (2007). When an invention combines two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does. *Id.* at 1737. Further, the relevant inquiry is whether the prior art suggests the invention and whether the prior art provides one of ordinary skill in the art

with a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988). Also, evidence of unexpected or unobvious results is objective evidence of nonobviousness, and may be used to rebut a *prima facie* case of obviousness. *In re Wagner*, 371 F.2d 877 (C.C.P.A. 1967); M.P.E.P. § 716.02.

First, as described in detail above, Botzolakis fails to teach or suggest at least one element of independent claim 1 – the freeze-drying of the admixture of a placebo cushioning component and active-loaded particles to form the active cushioning component. Moreover, Habib fails to remedy this deficiency of Botzolakis. Habib teaches freeze-drying of the cushioning component alone prior to combining it with the biologically active ingredient-loaded beads (see, *i.e.*, col. 65, *ll.* 18-21). Habib does not teach or suggest freeze-drying of the admixture of the cushioning component and biologically active ingredient-loaded beads to form the active cushioning component as required by the claims of the present invention. In addition, nowhere does Habib teach or suggest freeze-drying of the active-loaded particles alone or together with the placebo cushioning component. In fact, Habib asserts that “the means for preparing the biologically active ingredient-loaded beads is not critical” for the invention of Habib (col. 30, *ll.* 39-41). Thus, the combination of Botzolakis and Habib fails to teach or suggest at least one element of the claimed invention.

Moreover, as described in the specification as originally filed, the freeze-drying of the admixture to form the active cushioning component creates the unexpected cushioning characteristic of the active cushioning component (see the specification at page 16, paragraph [0085]). Such freeze-drying of the admixture produces a very porous layer of cushioning component that surrounds the active-loaded particles, which allows coatings of the active-loaded particles to withstand compression forces as high as 1000 kg or more during the tableting process, and creates a non-hygroscopic active cushioning component that does not require any special handling or packaging (see the specification at page 16, paragraph [0085]). Thus, the freeze-drying step of the pending claims produces a composition that possesses characteristics that are unexpected and non-obvious in view of Botzolakis and Habib, alone or in combination.

Therefore, for at least these reasons, Applicants assert that claims 1-11 are not obvious over Botzolakis in view of Habib, and respectfully request that this rejection be withdrawn.

B. Claims 1-11 Are Patentable Over Habib in View of Botzolakis

Claims 1-11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Habib in view of Botzolakis. Applicants respectfully disagree, for the reasons discussed below.

Habib teaches freeze-drying of the cushioning beads alone, prior to combining them with the biologically active ingredient-loaded beads (see, *i.e.*, col. 65, *ll.* 18-21). Habib fails to teach or suggest at least two elements of independent claim 1. First, Habib fails to teach or suggest combining the placebo cushioning component with the active-loaded particles (prior to freeze-drying). Second, Habib fails to teach or suggest freeze-drying of the admixture of the placebo cushioning component and the active-loaded particles to form the active cushioning component of the claimed invention. Moreover, Habib does not teach or suggest freeze-drying of the active-loaded particles.

Botzolakis fails to remedy the deficiencies of Habib. Botzolakis discloses combining a drug with microcrystalline cellulose (highly compactable filler), crospovidone (highly water-absorbing material) and water (see col. 3, *ll.* 36-53; and col. 4, *ll.* 10-25). However, like Habib, Botzolakis fails to teach or suggest freeze-drying of the admixture of the placebo cushioning component and the active-loaded particles to form the active cushioning component of the claims. Furthermore, like Habib, Botzolakis does not teach or suggest freeze-drying of the active-loaded particles. Thus, Habib and Botzolakis, alone or in combination, fail to disclose or suggest all elements of the claimed invention.

Therefore, for at least the foregoing reasons, Applicants assert that claims 1-11 are not obvious over Habib in view of Botzolakis, and respectfully request that this rejection be withdrawn.

V. **CONCLUSION**

Since all claim rejections are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with the Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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